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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,522	03/10/2005	Shinichiro Yokoyama	MOR-254-A	5175

48980 7590 05/14/2009  
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TROY, MI 48084

EXAMINER
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MEDWAY, SCOTT J

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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05/14/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@youngbasile.com  
audit@youngbasile.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,522	<b>Applicant(s)</b> YOKOYAMA ET AL.	
	<b>Examiner</b> SCOTT MEDWAY	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/21/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the second Office Action based on the 10/527522 application filed 03/10/2005. Examiner acknowledges the reply filed 02/09/2009. Examiner additionally acknowledges the amendments to the claims and withdraws the objection thereto.

Claims 1, 2 and 4 are currently pending and are considered below. Claims 1, 2 and 4 have been amended.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "one or more bypass holes in a position closer to a tail end than the two balloons" is unclear since it is not known what is meant by "closer to a tail end than the two balloons". The reference point for "the two balloons" is indefinite because the point may be located at any portion encompassed by the two balloons, thus the reference point is not clearly established. Additionally, it is not known what is meant by "a tail end", since the structural element which is intended to possess a "tail end" is not clearly established.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**4. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (U.S. Pat. 5,135,484) in view of Levin et al (U.S. Pat. 6,592,567 B1, hereinafter "Levin").**

Regarding claim 1, Wright discloses a device for infusion therapy, showing in Fig. 3 to comprise a balloon catheter; a guide wire (56) to be inserted into a guide lumen (50) that guides the catheter body to a target position; a plurality of lumens (e.g. 60, 72) extending along an axis; heart pulsation detection means (col. 3, lines 22-25); and two expandable balloons (48). The plurality of lumens comprise an infusion lumen (60), which can supply a drug-like slurry to the outside of the catheter, is shown in Fig. 3 to have an infusion hole located in between the two balloons. The device comprises: balloon lumens (44) communicating with the insides of the two balloons to control expansion of the balloons; a bypass lumen (72) which is located outside of the two balloons, which contains a bypass hole (see Fig. 3; the bypass hole being located at the distal end opening of the device, thus closer to the tail end than to a point encompassed by the two balloons), and which bypasses the occluded area as shown to allow blood flow (col. 4, lines 44-46); and a lumen (e.g. 56, 72) which serves as a guide lumen to communicate with the outside of the catheter body and a bypass lumen (col. 4, lines 41-

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50). It is noted that Wright does not disclose stroke means for causing the guide wire to stroke in synchronization of the pulsation of the heart. Levin discloses a balloon catheter comprising means for moving in a back-and-forth stroke in synchronization with the pulsation of the heart (col. 8, lines 51-58). Since Wright discloses the desire to permit a high level of fluid flow around a treatment zone via bypass lumen and to detect and monitor fluid flow and pressure in a vessel (col. 3, lines 22-25; col. 4, lines 54-56; col. 5, lines 25-27) and to use for instance a piston pump (col. 5, line 36) to pump material to and from the vessel site, it would have been obvious to one of ordinary skill in the art at the time of the invention to consider adapting the flow detection system present in the device of Wright for integrating the means to control stroke of a guide wire (for instance as a pump-like store-and-release mechanism as taught by Levin, to ensure a high level of blood flow through the bypass lumen.

Regarding claim 2, Wright discloses the device to have a lumen (44) which inflates both of the balloons shown in Fig. 3 (col. 3, lines 1-2).

**5. Claim 4 is rejected as being unpatentable over Wright (U.S. Pat. 5,135,484) in view of Levin et al (U.S. Pat. 6,592,567 B1, hereinafter "Levin"), further in view of Corday et al (U.S. Pat. 4,689,041, hereinafter "Corday") or Hall et al (U.S. Pat. 6,196,230 B1, hereinafter "Hall") or Smits (U.S. Pat. 6,549,812 B1).**

It is noted that while the patent of Wright discloses the use of the device in the coronary artery, it does not disclose the device for insertion into a coronary vein. The patents of Corday, Hall and Smits disclose the use of balloon catheter systems for

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introduction of drugs or for occlusion or removal of material from a vessel where the devices are used for insertion into a coronary vein. Accordingly, one of ordinary skill in the art at the time of the invention would be prompted to modify the combination of Wright in view of Levin so that it can be used in the coronary vein, which is a function considered obvious in view of the conventionality of this particular intended use (e.g., for infusing material into a vessel).

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1 and 2 have been considered but are not persuasive.

In response to Applicant's argument that the phrase "*one or more bypass holes in a position closer to a tail end than the two balloons*" is not taught, suggested or rendered obvious by neither Wright nor Levin, Applicant is directed to the above rejection noting that a bypass lumen (72) of Wright has a bypass hole at its distal end, which is closer to a tail end of a portion of the device than to a position encompassed by the two balloons.

In response to Applicant's argument that the phrase "*the balloon catheter previously combined with the guide wire is inserted into a coronary vein in reverse of the blood flow and adjusted so that a blood vessel area surrounding the lesion is placed between the two balloons*" is not taught, suggested or rendered obvious by neither Wright nor Levin, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

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patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The prior art structure clearly meets the structural limitations of the claimed invention and is fully capable of performing the intended use.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/  
Examiner, AU 3763  
05/07/2009

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763